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# FDA on Food Additives and Salt

David A. Wirth
*Boston College Law School*, wirthd@bc.edu

tons of garbage per day the resource recovery plant will burn. But local food merchants complain the existing plants already attract vermin and give off noxious odors.

Recent scientific reports prepared for the Hunts Point Environmental Protection Council and for the office of New York City Comptroller Harrison Goldin warn that operation of resource recovery facilities may also produce traffic and noise problems. Additionally, they cite risks of contamination to local air, water, and, in the case of the Hunts Point project, to the metropolitan food supply due to vermin and emissions of odor, microorganisms, and toxic chemicals, of which the carcinogen dioxin is only one. All these, say the scientists, are unavoidable by-products of resource recovery plants.

Krasdale Foods' management is also worried about the effects a plant's emissions might have on area employees, the public environment, and the food traffic at the market. As a result, Krasdale is holding in abeyance expansion plans that would have brought 300 new jobs to the depressed neighborhood.

The Sanitation Department plans to include electrostatic precipitators to control emissions of odors and chemicals. To appease environmentalists and alarmed local residents such as those who vocally protested the first proposed facility at the Brooklyn Navy Yard, resource recovery planners cite Europe's success with garbage burning plants. But resource recovery opponents say that, so far, inadequate measurements have been made on the effects of the European plants' emissions.

And the argument goes on, no less heated, fought with scientific studies and refutations of studies. The scientists who oppose the resource recovery plants are not against them in principle. Rather, they agree that further study is necessary to first determine emission safety standards. They also suggest that the planners may learn lessons from the alternate waste disposal technology that Japan has developed at great cost.

When selecting sites for city plants, the scientists recommend more cautious evaluation of the risks to public health. Most favor implementing the Sanitation Department's new strategy of disposing of solid wastes at sites away from populated areas and food distribution centers.

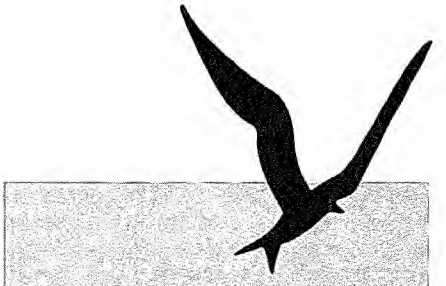
In a report to Comptroller Goldin, Neil Goldstein, a Sierra Club representative and former assistant commissioner of air resources, contested some study methods and assumptions on health risks made by the Sanitation Department's consultant, Camp Dresser & McKee. Goldstein took a hard line, saying, "Carcinogens are not subject to threshold safety levels . . . no human exposure level is safe."

The risk is also a financial one for investors in the Hunts Point resource recovery project in the event of its failure, Krasdale's Balka noted, as funding for the plant will come primarily from the issue of industrial bonds. Even a short-term closing by federal environmental inspectors could have a tremendous ripple effect beyond the health and monetary costs to be borne by food market merchants, the 7,000 employees there, and 100 plant workers. The city stands to lose revenues from taxes, license fees, and rent. Consumer confidence could be lost. Peripheral industries servicing the market, such as refrigeration, trucking, and shipping, would also be adversely affected.

Food merchants are "deeply concerned," according to Al Nagelberg. "If we got closed down by a dioxin-type situation, even for a few days, there would be fortunes lost across the country," he said. Referring to the upheaval caused by the return in April of suspect cases of gefilte fish when dioxin contamination was discovered at Lake Michigan, Balka said, "This could be gefilte fish times ten-thousand!"

The alternative would be no less ominous, Nagelberg warned. "The market's leaving because of a garbage plant would put a big dent in the local economy and a big dent in the city's investment in the area."

**RACHAELE I. RAYNOFF**, previously with NBC news, is a New York-based free lance who writes frequently on environmental issues.



**LAW**

## *FDA on Food Additives and Salt*

**David A. Wirth**

Recent Food and Drug Administration (FDA) actions could affect the incidence of cancer and heart disease in the United States. First, the agency has sought to circumvent the Delaney Clause, the strictest anticancer provision in federal law. Second, it has relied on a voluntary program for labeling salt, excessive consumption of which is linked to cardiovascular ailments.

The Delaney Clause,[1] first enacted in 1958, protects the public from carcinogenic additives to food. Public attention has tended to focus on the application of the clause with regard to such substances as cyclamates, nitrites, and saccharin. There has been less awareness, however, of the untold numbers of sus-

pect food additives and colorings that industry has never sponsored for approval because of the Delaney Clause and that consequently have never entered the food supply.

Until recently, FDA consistently interpreted the clause to prohibit the addition of carcinogens in *any* amount. In 1982, however, FDA reversed its policy to permit approval of additives containing detectable amounts of unintended carcinogenic contaminants that the agency calls "constituents"—impurities, residues, starting materials, or by-products—so long as the presence of these materials is undesired or they do not contribute to the function of the additive.[2]

The concept of an unintended constituent, however, has minimal relevance when the concern is for health effects. Exposure is exposure, and the fact that industry did not choose to add a contaminant that is unavoidably present in the final product provides little consolation to exposed members of the public.

The Delaney Clause is based on the established principle that there is no safe level of exposure to a cancer-causing substance. That scientific theory is as valid today as it was when the clause was first enacted. The Congressional Office of Technology Assessment, for instance, has recently reaffirmed the principle that there is no "risk-free" dose for a group of people composed of diverse individuals."[3] If anything, recent evidence establishes an even stronger link between diet and cancer than was apparent at the time of that statement.[4]

Unlike environmental contaminants, food additives and colorings always involve intentional exposure. Most food additives are either interchangeable or altogether unnecessary, and colorings are strictly cosmetic. It consequently makes no sense to permit a food additive or coloring to be used when there is the slightest question about its safety. This is precisely the congressional policy that was clearly articulated in the Delaney Clause.

With improved technology that can detect chemicals in lower and lower amounts, and with proof that a growing number of chemicals are carcinogenic, industry claims that the clause is no longer practical in that it could require some supposedly useful additives to be banned. Congress, however, has refused to alter the stringent Delaney anticancer policy on several occasions, despite attacks relying on these or similar positions.

The public also has not accepted these arguments. On the contrary, studies show that consumers are highly suspicious of the safety of foods that have been doctored with additives and colorings.[5] These additives may be useful to industry, but most of them do not benefit the public very much. The other side of the coin is that the public bears all the health risks associated with their use.

***In both of these cases—food additives and the labeling of salt content—FDA has failed to fully implement its mandate of protecting the public health.***

As a result of its policy reversal, FDA has approved four colorings containing demonstrated carcinogens.[6] Two of these, D&C Reds Nos. 6 and 7, are contaminated by the carcinogen *p*-toluidene. These colors are used in over 20 percent of lipstick formulations, and FDA estimates that a significant amount of lipsticks containing these dyes—over 75 percent—is ingested after application. The agency has not even revealed the identity of the carcinogenic contaminant in its fifth and most recent application of the policy, claiming that the contaminant's identity is protected from disclosure as confidential business information, a so-called trade secret.[7]

FDA's record on the labeling of processed foods for salt content also reflects the current administration's reluctance to move forward with new initiatives necessary to protect the public health. Excessive intake of sodium, the most common source of which is table salt, has long been known to be a primary contributing factor to high blood pressure, heart attacks, and strokes, the principal causes of death among Americans. Salt added to processed foods provides the single greatest contribution of sodium to the American diet. Today approximately 40 percent of consumers are attempting to lower their sodium intake.[8] This is often difficult to do. A single serving of condensed soup, for example, can contain a dose of sodium that is more than half the amount the National Academy of Sciences has described as "safe and adequate" for an entire day.[9]

Labeling, which involves the dissemination of information about a product, is one of the least burdensome forms of regulations. FDA nonetheless proposed a largely voluntary salt labeling program,[10] despite widely voiced concerns that a mandatory program was necessary to enable consumers to control salt intake from as many sources as possible. "Industry just isn't going to do it on its own," says Dr. Jere Goyan, former commissioner of FDA. "With an issue like this, which is in the best interest of the American people, we should not rely on voluntary efforts."

The agency's program would require sodium labeling only when packages include nutrition labeling, which in most cases is voluntarily supplied. This allows most manufacturers of processed foods the option of discontinuing voluntary nutrition labeling altogether if they find the requirement to specify sodium levels too burdensome or too threatening to their competitive positions in the market.

In both of these cases, FDA has failed to fully implement its mandate of protecting the public health. In its "constituents" policy, FDA has asserted to the public that certain food additives and colorings are safe. In actuality, however, Congress has already made a determination that all additives containing carcinogens should be prohibited.

On the sodium issue, by contrast, the agency has recognized that consumers can exercise control over a factor affecting their own health. FDA's labeling proposal, however, does not go far enough in assuring access to information essential to meaningful consumer choices. The agency should rethink its approaches to both issues in order to produce policies that more effectively further its mission of protecting the public health.

**DAVID A. WIRTH** is a former attorney and legal fellow with the New York office of the Natural Resources Defense Council, Inc.

## NOTES

1. There are actually three Delaney Clauses addressing, respectively, food additives, 21 *U.S.C.* § 348 (c)(3)(A); color additives, 21 *U.S.C.* § 376(b)(5)(B); and animal drugs, 21 *U.S.C.* § 360b (d) (1) (H).
2. See 47 *Fed. Reg.* 14464 (April 2, 1982).
3. *Assessment of Technologies for Determining Cancer Risks from the Environment* 12 (1981).
4. See, for example, National Academy of Sciences, *Diet, Nutrition, and Cancer* (1982).
5. A recent Harris study, for example, found that about eight of every ten consumers feel "very or somewhat closely" described by the statement that "some ingredients added to processed foods may be harmful or unsafe to eat." The survey found, moreover, that nearly three of every four consumers avoid buying certain foods because of concerns about their safety. Food Marketing Institute, *Trends—Consumer Attitudes and the Supermarket* 35 (1983).
6. D&C Green No. 6, 47 *Fed. Reg.* 14138 (April 2, 1982); D&C Green No. 5, 47 *Fed. Reg.* 24278 (June 4, 1982); D&C Reds Nos. 6 & 7, 47 *Fed. Reg.* 57681 (December 28, 1982).
7. 48 *Fed. Reg.* 37615 (August 19, 1983).
8. Department of Health and Human Services Press Release (July 14, 1983).
9. See 47 *Fed. Reg.* 26580, 26581 (June 18, 1982).
10. Ibid.